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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,017	05/03/2006	David L Morris	SPRUS1120 (026470-0301)	8753

30542 7590 10/02/2008

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EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,017	MORRIS, DAVID L	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) *19,20,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I, drawn to a method of isolating normal hepatocytes, in the reply filed on 07/02/2008 is acknowledged. The traversal is on the ground(s) that a search of one set of claims (e.g., the Group II claims, directed to methods of treating a liver disorder employing hepatocytes obtained by the Group I methods) would, of necessity, require a search of the other set of claims (e.g., the Group I claims, directed to methods of isolating normal hepatocytes). Accordingly, Applicant argues, no savings of PTO resources will be realized by maintaining the requirement for restriction. This is not found persuasive because, although the invention of Group II uses isolated hepatocytes, Group II is drawn to a method of treatment which requires additional and distinct searches and considerations under 112, first paragraph, which searches and considerations are not required for the elected invention of Group I. For these reasons, examining the two inventions together would be a burden for the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17 and 18 have been cancelled.

Claims 19, 20, 24, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 1-16 and 21-23 are under examination.

Specification

2. The disclosure is objected to because of the following informalities: this application contains sequence disclosures (page 11) that are encompassed by the definitions for nucleotide sequences set forth in 37 CFR 1.821 (a)(1) and (d). However, the specification fails to comply with the requirements of 37 CFR 1.821 (a)(1) and (d), because the sequence identifiers, preceded by SEQ ID NO are missing.

Appropriate correction is required.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Applicant is advised that should claims 1-7, 15, and 22 be found allowable, claims 8-14, 16, and 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case," isolating" and "preparing" have the same meaning and the recitation of "preparing for transplantation" in the preamble is an intended use which is not considered a claim limitation because, since all limitations of the claimed invention are set forth in the body of the claims, such an intended use does not state any distinct definition of any of the claimed limitations.

5. Applicant is advised that should claim 1 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; similarly, should claim 1 be found allowable, claim 23 will be objected to as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-16 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kay et al. (U.S. Patent No. 6,660,905), in view of each Caruana et al.

(Cryobiology, 1999, 38: 165-168; Applicant's IDS), Hui et al. (J. Hepatobiliary Pancreat. Surg., 2001, 8: 1-15, Applicant's IDS), and Myers et al. (WO 96/09876).

Kay et al. teach a method of isolating normal hepatocytes, wherein the hepatocytes are isolated from fresh human liver tissue and separated from unwanted cells via magnetic bead separation (claims 1, 8, 15, 16, 22, and 23) (column 8, lines 1-10).

Kay et al. do not teach isolating their hepatocytes from liver samples obtained by hepatectomy performed for tumor resection (claims 1, 2, 8, 9, 22, and 23), nor do they teach removing macroscopic evidence of the tumor-affected tissue before the magnetic separation (claims 3 and 10). Caruana et al. teach that normal hepatocytes could be obtained from liver samples obtained via hepatectomy for tumor rejection, wherein, prior to hepatocyte isolation, the macroscopically visible tumoral tissue is separated from the normal tissue (p. 165, column 1, p. 166, column 1). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the method of Kay et al. by substituting their liver tissue with a sample obtained via hepatectomy as taught by Caruana et al. to achieve the predictable result of obtaining hepatocytes. Although Kay et al. and Caruana et al. do not specifically teach using a magnetic bead coated with a monoclonal antibody recognizing an epitope on the surface of the normal hepatocytes (claims 5, 6, 12, 13) or a monoclonal antibody recognizing the tumor cells (claims 4, 7, 11, and 14), they do teach that separation of target cells from a cell mixture can be obtained by using monoclonal antibodies specific for either the target cells or the unwanted cells (see Kay et al., column 13, lines 5-19). Based on these teachings, it

would have been obvious to one of skill in the art, at the time the invention was made, to perform the magnetic separation with beads coated monoclonal antibodies directed to either hepatocytes or contaminating tumor cells to achieve the predictable result of enriching the cell population in hepatocytes.

Kay et al. and Caruana et al. do not teach an artificial liver support comprising their isolated hepatocytes (claim 21). However, at the time the invention was made, artificial liver supports comprising isolated normal hepatocytes were taught by the prior art (see Hui et al., Abstract, p. 3, column 2, p. 4; Myers et al., Abstract, p. 6, lines 33-37, p. 7). It would have been obvious to one of skill in the art, at the time the invention was made, to use the isolated normal hepatocytes of Kay et al. and Caruana et al. to obtain an artificial liver support, with a reasonable expectation of success. One of skill in the art would have been motivated to do so because the art teaches that such devices could be used for the treatment and support of patients suffering from liver diseases (see Myers et al., p. 1, lines 9-18, Hui et al., p. 12, columns 1 and 2). One of skill in the art would have been expected to have a reasonable expectation of success in doing so because the art teaches that isolated hepatocytes can be successfully used to obtain artificial liver supports.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

8. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD
/Ileana Popa/
Examiner, Art Unit 1633